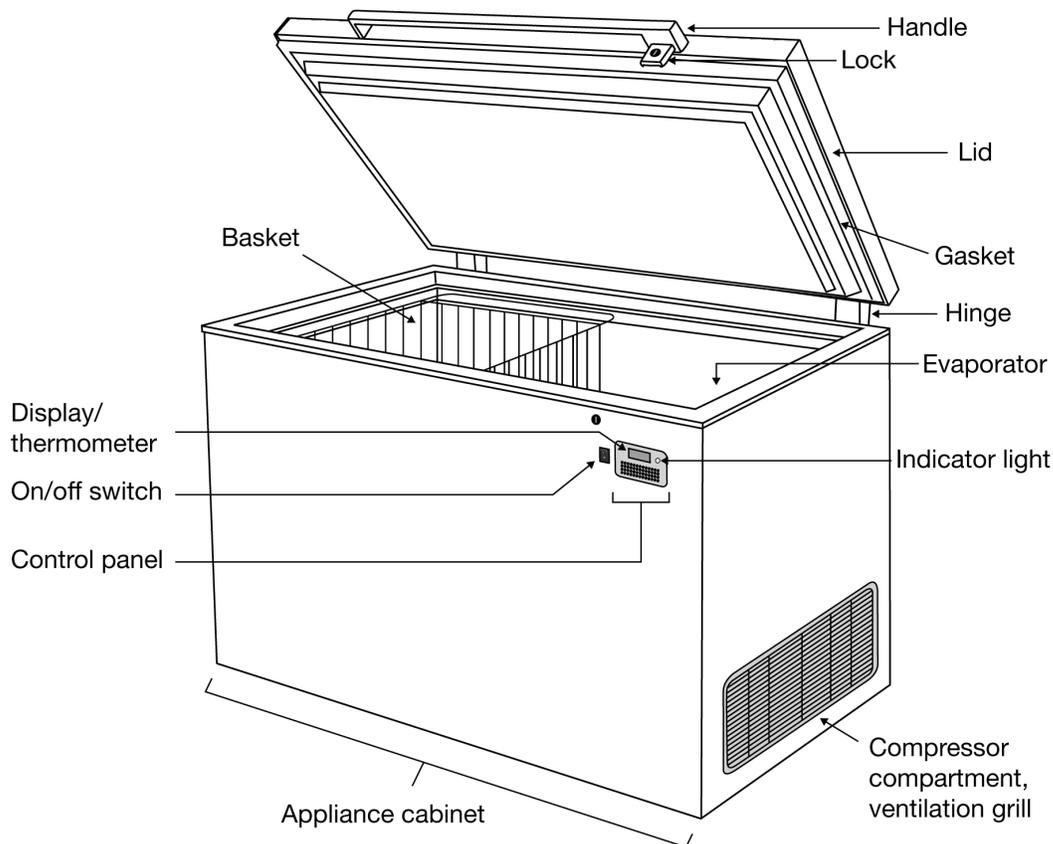


TERMS AND DEFINITIONS

POST MARKET MONITORING – COLD CHAIN EQUIPMENT

* SEE APPLICATION NOTES BELOW FOR ASSESSOR INPUT INSTRUCTIONS



A

Absorption - appliances that use a heat source such as gas or kerosene to drive the cooling system.

Alternating current (AC) - electric current that reverses direction periodically. AC appliances are typically 220 VAC, 50 or 60 Hz or 120 Vac, 60 Hz.

Appliance – general term to describe any vaccine refrigerator, vaccine freezer, water-pack freezer or combined vaccine refrigerator and water-pack freezer as specified by WHO PQS.

Appliance to power connection - see “Power cable”.

Audible alarm – monitoring device that emits sound under specified conditions or operations. Specify conditions for the alarm from the following possibilities: temperature, voltage, power, autonomy, holdover.

Autonomy (refrigerator): time in hours that a solar-powered refrigerator, or combined refrigerator and water-pack freezer, can maintain the vaccine load between +2°C and +8°C under low solar radiation conditions (e.g. rain).

Autonomy (freezer): time in hours that a solar direct drive water-pack freezer can maintain the minimum required capacity of fully frozen water-packs under low solar radiation conditions (e.g. rain).

Autonomy/holdover gauge – monitoring device displaying estimated time remaining in thermal storage system.

B

Basket – bin used to organize or support items including vaccines and diluents.

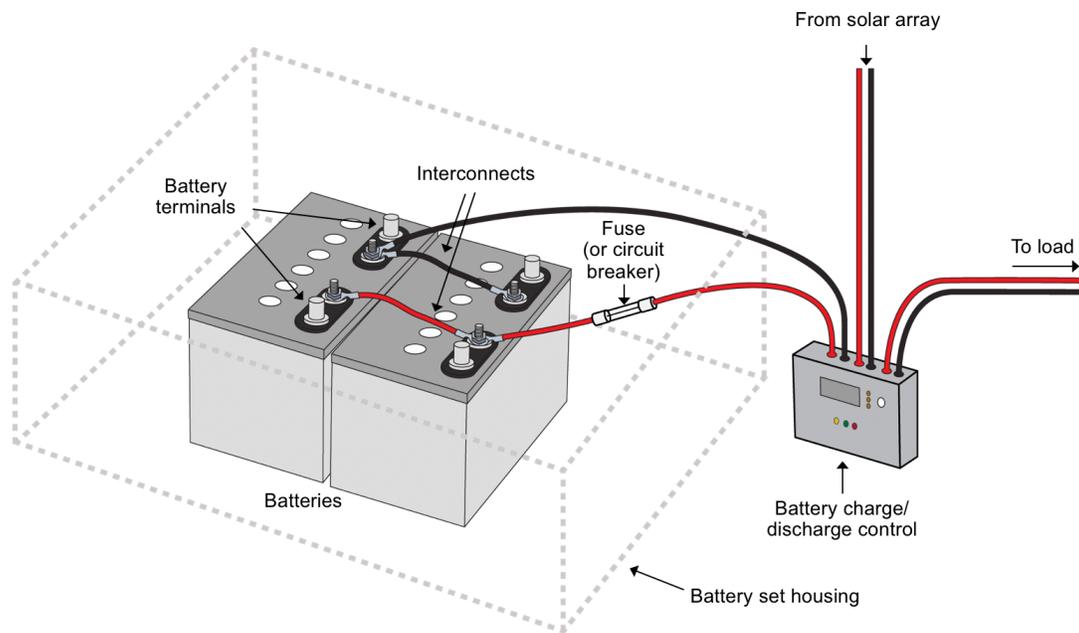
Battery - chemical energy storage device for DC electricity. Batteries are found in RTMD, 30 DTR, some thermostats, some types of solar power systems and some energy harvest load devices.

Battery charge/discharge control - electronic device to regulate the power in and power out of a battery bank that is recharged with solar electricity (aka “solar control”, “battery charge regulator”).

Battery set housing – enclosure to protect a battery from accidents and unauthorized contact.

Battery terminal - points where positive and/or negative electrical connections are fastened to a battery.

Battery voltmeter – monitoring device, displaying voltage of battery, typically in real time.



Break- material or component separation into pieces as a result of a blow, shock, or strain.

Build quality - issues related to appliance durability.

Burner/boiler – absorption refrigerator component where heat is applied to boil refrigerant.

Bypass diode - diode connected across one or more solar cells in a photovoltaic module such that the diode will conduct if the cell(s) become reverse biased. It protects these solar cells from thermal destruction in case of total or partial shading of individual solar cells while other cells are exposed to full light.

C

Cabinet - general term for the appliance enclosure.

Capacitor – device for accumulating and discharging an electric charge. Capacitors are found in refrigeration equipment where a short burst of electricity is needed to start the compressor motor.

Capillary tube – gas filled, thin tubing used either in thermostat control or in refrigerant piping to control the flow of refrigerant in the cooling system.

Circuit breaker – mechanical switching device, capable of making, carrying and breaking electric currents under normal circuit conditions. Circuit breakers are found as

overcurrent protection devices in some appliances, energy harvest accessories and power systems.

Combiner - electrical connection enclosure or fitting where solar module interconnects are joined to the solar array output cable. Combiners may be enclosure boxes or weather tight branch circuit connectors.

Compressor - basic item of equipment for mechanically increasing the pressure of a gas.

Compressor electronic unit - electronic control unit matched to a specific appliance compressor. Also known as “electronic unit”, “electronic box”, “electronic control unit” or “ECU” or “controller for compressor”.

Condensation - water which collects on a cold surface when humid air is in contact with it.

Condenser – refrigeration heat exchanger in which a vapor is liquefied by removal of heat.

Control panel - assembly incorporating all the regulation means necessary for the operation of an installation, with or without corresponding indicator(s). An appliance control panel could include appliance on/off switch, thermostat and LED indicator lights.

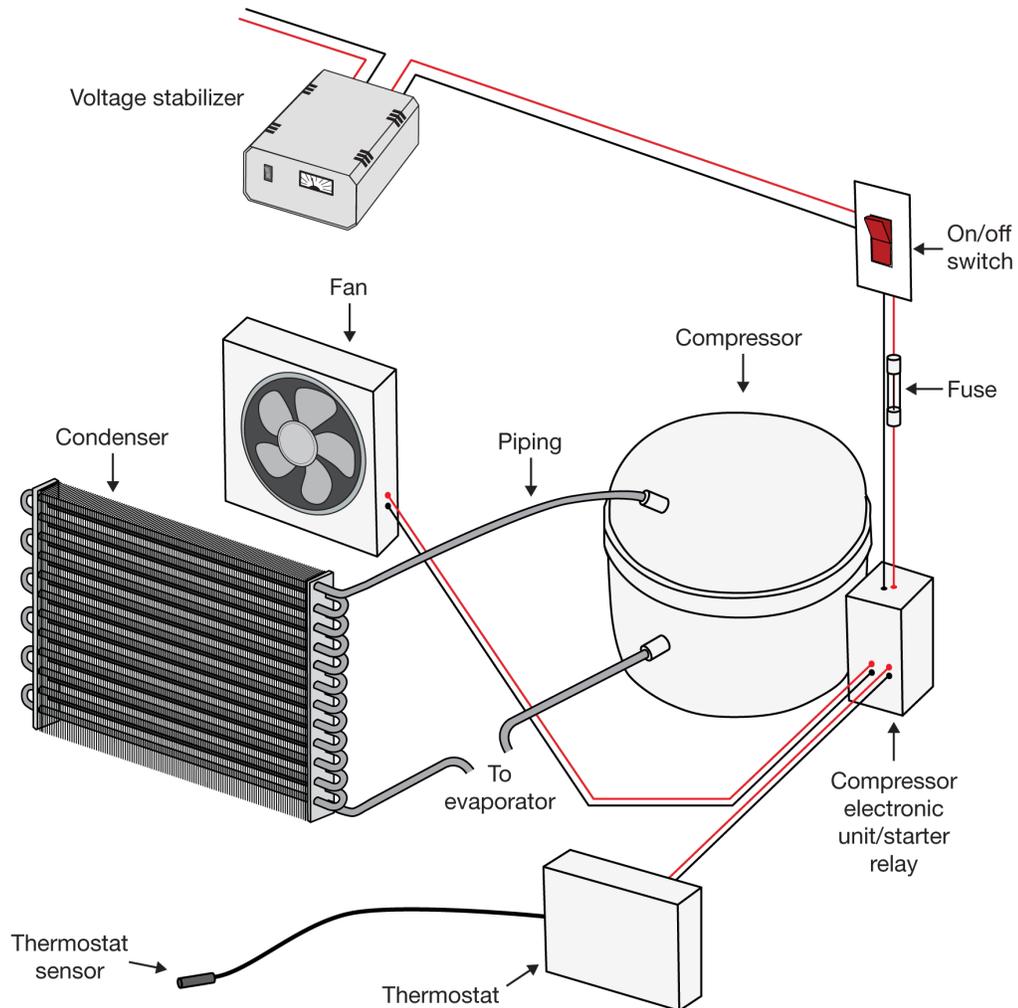
Connectivity- the ability of a computer, program, device, or system to connect with one or more others.

Cool-pack - A water-pack pre-cooled to a temperature between + 2°C to +8°C before use. See “water-pack”.

Corrosion - the irreversible damage or destruction of material due to a chemical or electrochemical reaction. Examples include aluminum oxidation, iron rust and plastic melt.

Coupler system - locking female and male coupler system with minimum IP rating of 65 (“plug and play”). Couplers are used where solar modules interconnect and where the solar array cable connects to the appliance.

Crack – a material split without breaking apart.



D

Daily temperature report – written record of appliance internal temperatures. Traditionally entered twice per day by health worker.

Damage - injury or harm to a component or system that reduces function, value or usefulness. Input “Damage” and refine input by inputting a secondary cause from this selection:

- abuse
- factory concealed
- factory observable

impact
insect
installation
misuse
rodent
shipping handling
shipping sea freight
shipping trucking
shipping storage
sunlight
water

Degradation- deterioration of a material or process.

Direct current (DC) - Electric current flowing in only one direction. DC appliances are typically solar powered and 12 or 24 VDC (when battery powered) or up to 45 VDC in solar direct drive appliances. DC accessories can operate on small battery systems where voltages are often 5 VDC or less.

Direct observation - a method of collecting evaluative information in which the evaluator watches the subject in its usual operating environment without altering that environment.

Disintegration- the process of losing strength or cohesion.

Display - panel assembly indicating operation and control status of an installation. An appliance display may include temperatures, power on light and error reports.

Door – operable entry into an upright appliance.

Door openings – each time an appliance interior is exposed to ambient air.

Drier - device for removing moisture from the refrigerant.

E

Electric cabling - see “wiring” and “power cable”.

Energy harvest - collection, distribution and use of surplus solar direct drive appliance electricity for loads in addition to an immunization appliance.

Energy harvest control (EHC) - accessory control device and/or system to enable the use of surplus solar photovoltaic electricity for powering other electricity consuming devices (loads) in addition to an immunization appliance.

Equipment management system (EMS) – component assemblies for advanced monitoring and communication of cold chain equipment (CCE) performance, events and alarms across administrative levels of the cold chain.

Evaporator - part of a refrigeration system in which the refrigerant evaporates by absorbing heat from the contacting fluid.

Excursion – deviation from a specified temperature range.

F

Failure - condition of not meeting the intended performance or safety requirements, and/or a breach of physical integrity. A failure is corrected by repair and/or calibration. (WHO VMH).

Failure cause – process that leads to a failure. Assessors are to input failure causes from the following selection:

- break
- build quality
- corrosion
- cracking
- damage (see additional damage definitions)
- degradation
- disintegration
- hot spot
- incomplete
- insufficient capacity
- lack of maintenance
- leak
- missing
- misplacement
- open circuit
- orientation
- outage
- power quality
- power tampering
- shading
- short circuit
- soiling
- tampering
- unauthorized use
- ultraviolet degradation
- voltage (low)

Failure consequence - way (or ways) in which a failure mode impacts intended performance.

Failure effect - description of what happens when a failure mode occurs.

Failure mode - way failure occurs. A failure mode may be defined by the function lost or other change(s) that occurred.

Failure symptom - identifiable or measurable physical condition by which a potential failure can be recognized.

Fan - rotary machine which maintains a continuous flow of air (based on IIR). Appliance fans are used to circulate air over condensers and may also be used internally to control cabinet temperatures.

Firmware - computer programs contained permanently in a hardware device (such as a read-only memory).

Flue – metal duct for carrying away combustion gases and particulates. Found on absorption appliances.

Flue baffle – metal insert in flue to enhance heat transfer to absorption refrigerant.

Flue brush – metal bristle cleaning tool for absorption appliance maintenance.

Freeze alarm - any time vaccine storage compartment is below -0.5°C.

Freeze excursion time - excursion event during which a vaccine is exposed to temperatures outside the range(s) prescribed for storage and/or transport.

Freezer compartment – distinct segment of an appliance used for freezing and storing vaccine or freezing and storing water-packs.

Frequency of freeze alarms per month - total number of freeze alarm events recorded in a month. Specified by manufacturer and appliance model.

Frequency of heat alarms per month - Total number of heat alarm events recorded in a month. Specified by manufacturer and appliance model.

Functional status - device operational categorization. Per inventory or data analysis (metadata).

Fuel disruption – anytime fuel is unavailable for an absorption appliance. Specify circumstance (e.g. fuel shortage, budget shortage, diversion to other uses).

Fuse - electrical safety device containing a material which melts at a predetermined temperature, thereby relieving the (overcurrent) pressure. Fuses are found in appliances, accessories and systems.

G

Gasket – component that ensures the air tight sealing of an appliance opening (door or lid).

Grounding system - all the electric connections and devices involved in the earthing of an appliance, accessory or power system installation and equipment.

H

Handle - part that is designed to be held or operated with the hand.

Heat alarm - ten consecutive hours of continuous temperature excursions above +8°C in a vaccine storage compartment.

Heat excursions time - an excursion event during which a vaccine is exposed to temperatures outside the range(s) prescribed for storage and/or transport.

Heater - any device to introduce warming temperatures on or into the appliance. Heaters are used for absorption refrigeration to heat refrigerant and used for internal temperature control in compression refrigerators.

Hinge - jointed or flexible device that supports the turning or pivoting of a part, such as an appliance door.

Hinge cover – protection for a hinge.

Holdover - time in hours during which all points in the vaccine compartment remain between +2°C and +8°C, at the maximum ambient temperature of the temperature zone for which the appliance is rated, after the power supply has been disconnected. A WHO PQS specification.

Holdover gauge – monitoring device displaying estimated time remaining in thermal storage system.

Hot spot – unintentional solar cell overheating caused by shading, soiling or mechanical faults. Detection is sometimes possible through visual inspection for evidence of heat damage but may require thermal imaging equipment and advanced techniques.

Hybrid power system – two or more sources of power combined in a single system. A health facility powered by a diesel generator coupled with solar electricity is an example of a hybrid power system.

I

Ice-lined refrigerator - A compression cycle refrigerator with an internal lining surrounding the storage that is filled with ice, cold water, or other coolant. When the electricity supply fails, the ice, cold water or coolant keeps the refrigerator cool for a minimum of 20 hours without power.

Ice pack - water-pack frozen to a temperature between -5°C and -20°C before use. See “water pack”.

Incomplete – unfinished works or undelivered goods. See also “Missing”.

Indicator light – lamp showing operating condition of some equipment or status of some metric. Appliances are required to use indicator light(s) to alert users of cooling system operation.

Installation - the completed, fully assembled and commissioned appliance and/or power.

Installation kit – assembly of components required to complete an appliance, accessory or system installation system and make ready for use. Example: PQS requires each SDD to be supplied with a solar power system installation kit that includes mechanical support structure, electrical wiring and hardware.

Instructions – manuals and other written or digital information indicating how a product is to be installed, operated, maintained, repaired and/or disposed of.

Insufficient capacity - failure to fully provide intended service. Examples of insufficient capacity include an appliance where its vaccine storage volume is exceeded or a solar power system that functions adequately until the rainy season when its solar array can no longer operate the compressor for enough hours per day to sustain acceptable temperature range.

Interconnect (electrical) - electrical wiring used to connect individual solar modules or batteries into larger groupings. Specify circumstance (e.g. solar array, battery bank). Also called “connector”.

K

Kit – assembly of components necessary to support the completed installation of an appliance, accessory or system. Example: WHO PQS E003 PV01 solar power system kits are required to be sufficient for the service provider to complete an installation.

L

Lack of maintenance – whenever preventive or corrective maintenance is not completed on schedule.

Lamp (absorption) – clear glass shield around burner flame in kerosene absorption appliance

Leak – escape of a liquid or gas from a hole or crack in a pipe or container.

LED – light emitting diode.

Lid - operable entry into a chest type appliance.

Lightning protection - complete system used to protect against the effects of lightning.

Load (energy) - Any end-use device in an electrical circuit (other than the primary appliance and EHC) that can consume power when the electrical circuit is energized.

Load (refrigeration) – any vaccine and related commodities that require cooling.

M

Missing – incomplete delivery or absent component, assembly, spare part, and/or instructions.

Misplacement - positioning of an appliance, solar array or accessory where performance or its service life is compromised. Cooling appliances placed in direct sunlight or placed where water damage can occur are examples of appliance misplacement.

Monitoring device - The device or system (e.g. EMS) that is receiving raw data collected from a monitored device.

Mounting hardware - fasteners to attach support structure to solar module and attach support structure to foundation.

O

On/off switch* - manual interrupter between an energy consuming load and its' power or fuel supply. Specify circumstance (e.g. appliance on/off, power system on/off).

Open circuit - for a given terminal pair, electric circuit without a continuous path between the two terminals of the pair.

Orientation – magnetic bearing of a solar array. Generally, the front (glazed) surface of solar arrays in the southern hemisphere will face north while arrays in the northern hemisphere will face south.

Outage - interruption in supply of electric power.

P

Phase change material (PCM) – material, other than water, which changes state between solid and liquid or changes between two different solid crystallization states over a defined temperature range, absorbing or releasing heat during the phase change. This process is reversible and can be useful for thermal control in cold chain devices and products.

Piping - tubes for interconnecting the various parts of a refrigerant circulating system. Also called “tubing”.

Power adapter – electronic device to match power supply characteristics with load power requirements.

Power cable – electrical wiring that connects an appliance or accessory to an electricity source (aka “power lead”). Specify circumstance (e.g. appliance power cable).

Power cable connector – the fitting of a power cable that connects to power source cable or receptacle.

Power quality - characteristics of the electric current, voltage and frequency at a given point in an electric power system, evaluated against a set of reference technical parameters.

Power tampering - unauthorized diversion of power to any load other than a PQS prequalified immunization appliance or energy harvesting system.

R

Remote Temperature Monitoring Device (RTMD) - programmable temperature and event logging systems with integrated alarm, automatic transmission to a server, and data access through a web portal used for monitoring storage conditions at different levels of the vaccine cold chain.

Refrigerant – working gas or fluid that cools appliance and contents.

Removable insulation - thermal isolation material that can be manually moved in and out of position.

Root cause (analysis) - systematic process to identify the cause of a fault, failure or undesired event, so that it can be removed by design, process or procedure changes.

S

Safety valve - device which automatically shuts off the supply of gas to an absorption appliance when the pilot flame is extinguished.

Seal (sealant) - filling material typically used in and around penetrations into appliances and buildings found at wiring, tubing or mechanical device entries.

Sensor - device that senses either the absolute value or a change in a physical quantity and converts that change into a useful input signal. Temperature sensor(s) are an integral part of thermostat control.

Shading – shadows on solar array position that reduce incoming solar radiation. Solar siting tools can provide a shading analysis that instantly measure shading losses for each month of the year.

Shading analysis - means of quantifying the shading that may reduce the amount and duration of solar irradiance a site receives. This is important when checking that a site receives adequate solar power for solar refrigerators to operate effectively. See “shading”.

SD card - Secure Digital card (SD card) is a non-volatile form of flash memory for portable devices including cell phones. SD card may be found in some RTMD.

Shelf – flat, horizontal support member. Typically, appliance shelves are removable.

SIM card - Subscriber Identity Module card is a portable memory chip used in cell phones. SIM card may be found in some RTMD.

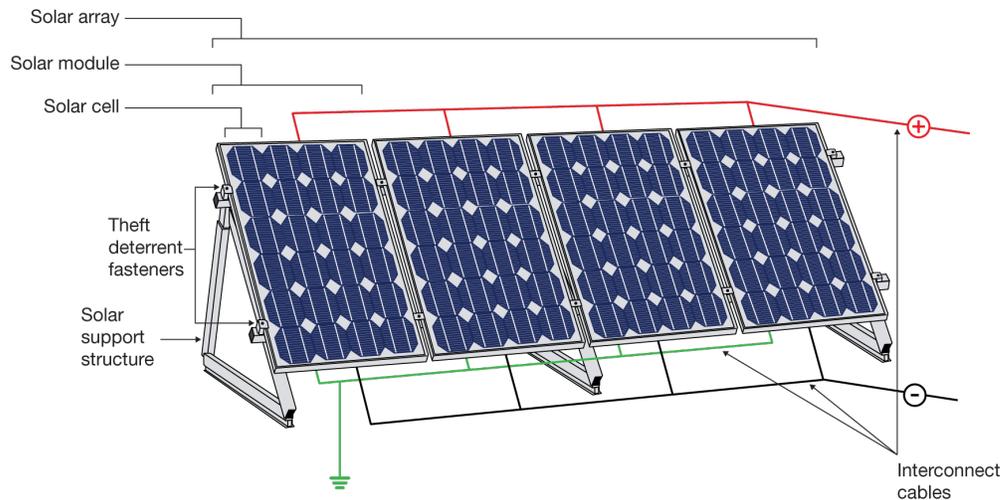
Short circuit - accidental electrical circuit in a device with no or low resistance when compared to that of the normal circuit, especially one resulting from the unintended contact of components and consequent accidental diversion of current. An intentional short circuit is one method used to measure the current of individual solar modules.

Software - the programs and other operating information used by a computer.

Solar array - solar module(s) mounted to a support structure, electrically connected with all other components as required, to form a direct current power producing unit. Also called “solar panel”.

Solar array cable - electrical wiring connecting a solar array to load.

Solar cell – basic solar subcomponent that generates direct current electricity when exposed to light. A solar module typically will require a quantity of interconnected solar cells that are encapsulated and not individually replaceable.



Solar direct-drive (SDD) - appliance that uses solar energy to freeze water or other phase-change material. This stored energy is then used to provide continuous cooling, even when solar irradiance is unavailable or limited (e.g. at night or on cloudy days).

Solar irradiance - amount of solar energy that arrives at a specific area at a specific time.

Solar module - a single complete assembly of solar cells with protective glazing (usually glass) and output terminals or cables. Also called (photovoltaic module, PV module, solar panel).

Solar power control – see battery charge/discharge control.

Solar support structure - mechanical assembly where solar modules are secured. WHO PQS specifies that support structures are metal and intended to attach to a foundation such as roof, concrete base or pole.

Solar power system - assembly of solar array, electrical cabling, support structure, control and energy storage (e.g. battery, water/ice or PCM).

Soiling – any dust, sand, bird droppings or other materials on the surface of a solar module that reduces solar power generation.

Spare parts consumption – quantity of replacement components used per month.

Starter relay - electrically operated switch used to transfer or disconnect power to an electric compressor motor.

Thermal storage - quantity of "cold" stored in sensible form (reducing the temperature of a mass of substance) or in latent form (e.g. the freezing of a liquid or a solution).

Thermocouple - heat sensing component of a gas safety valve used to confirm a pilot light is lit.

Thermometer – temperature measurement instrument. Appliance thermometers are both passive and actively powered by either mains, battery, solar power or ambient light.

Thermostat - device which automatically regulates the operation of a refrigerating system according to the temperature of the cabinet or of an evaporator.

Thermostat control card - electronic control logic assembly.

Thermostat sensor lead - electrical connection for transmitting information to a thermostat.

Thermostat tampering - unauthorized change to a temperature setpoint control or temperature sensor location.

Thermostat wiring - electrical connection for powering a thermostat.

Thirty Day Temperature Recorder (30 DTR) - Electronic refrigerator logger, with factory-programmed alarms and visual display for monitoring storage conditions in vaccine refrigerators over a 30-day period. The term 30-day temperature recorder (30 DTR) is used interchangeably.

Tilt - angle (degrees) of PV array as referenced to the horizontal.

Transformer - an electric energy converter without moving parts that changes voltages and currents associated with electric energy without change of frequency.

U

Unauthorized item - placement of anything prohibited in an appliance (e.g. personal food, drinks).

Unknown – when the cause of a failure is not determined.

Uptime (refrigerator) – percentage time per month that a refrigerator is functional and operating safely within +2 to +8°C range. Specified by manufacturer and appliance model.

V

Ventilation grill – opening in an appliance cabinet, electronic control or battery set housing to allow free flow of ambient air.

Voltage – electrical potential measured between two points. Low voltage conditions are known to prevent or hinder operation of some electrical components. Abnormally high or low voltage can damage some electrical components.

Voltage stabilizer - electrical device designed to reduce fluctuations in input voltage and frequency and ensure a stable electricity supply for refrigerators and freezers in situations where the supply voltage is subject to wide fluctuation.

W

Warm pack – water-pack typically stabilized at room temperature, up to a recommended maximum of +24°C. Warm-packs are used for the transport of freeze sensitive vaccines in countries where sub-zero temperatures are common. See “water pack”.

Water-pack - A flat, leak proof, plastic container, filled with tap water.

Wicks – fiberglass or cotton material that draws kerosene by capillary action to support a flame.

Wiring – general term for assembly made up of one or more insulated conductors, cables or busbars and the parts which secure their fixing and, if necessary, their mechanical protection.

Wiring connections - intentional electric contact between conductors. Both factory-made and field wiring connections are found in appliances, accessories and power systems.

Wiring terminals – mechanical connection points for electrical wiring.

*Application notes:

Note to reader, the following examples assume that the program/application for assessor observation inputs has input fields for both “Component” and “Failure cause” (up to two “Failure causes” inputs allowed).

Assessor Input instructions:

- a. In the “Component” field enter a component name. Only input components included in the Terms and Definitions.
- b. In the “Failure cause” field enter up to two observed causes or conditions. Only input observable causes/conditions included under “failure cause” in the Terms and Definitions.

Example 1: Ice lined refrigerators and SDD's have thermal storage. Damage or poor build quality can result in leaks of the thermal storage materials, usually water or phase change material.

An assessor observes thermal storage leakage and would enter:

- a. In "Component" field enter "Thermal storage"
- b. In "Failure Cause" field #1 enter "Leak"

Example 2: Wiring damage is observed from a variety of causes.

An assessor observes no voltage at the compressor electronic control and then observes wiring damage due to rodents and would enter:

- a. In "Component" field enter "Wiring"
- b. In "Failure Cause" field #1 enter "Damage"
- c. In "Failure Cause" field #2 enter "Rodent"

Example 3: Electrical problems can be difficult to diagnose, and only electrically qualified assessors are capable of safely carrying out electrical troubleshooting. The same is true for some types of refrigeration problems. When a problem cannot be diagnosed the assessor would enter the most observable "Component" problem, but the "Failure Cause" would be entered as "Unknown".

An assessor who finds that the thermometer on an ILR is not displaying a temperature may not be able to diagnose the cause and would then enter:

- a. In "Component" field enter "Thermometer"
- b. In "Failure Cause" field #1 enter "Unknown"

Example 4: Third party failure reports are useful but may not provide enough information. In some cases, these reports may be inaccurate. Assessors will rely on user and technician reports but must also utilize their skills of observation and investigation in order to more accurately define details.

A report states a refrigerator has failed due to a refrigerant leak. The assessor visits the site and a technician demonstrates that there is no refrigerant charge. The assessor also notes that the appliance condenser shows signs of an impact with observable damage that may have caused the leak. An assessor would enter two sets of observations:

Observation 1

- a. In "Component" field enter "Refrigerant"
- b. In "Failure Cause" field #1 enter "Leak"

Observation 2

- a. In “Component” field enter “Cabinet”
- b. In “Failure Cause” field #1 enter “Damage”
- c. In “Failure Cause” field #2 enter “Impact”

Example 5: A report states a solar direct drive refrigerator is not cooling. The users have cleaned the solar array and could find no apparent problems with shading or cable damage.

A trained and electrically qualified assessor visits the site and notes that the refrigerator is too hot, the power cable is connected, and it is switched on, but the compressor will not start under sunny conditions. The assessor then measures a typical voltage at the compressor electronic control. The qualified assessor then uses the LED diagnostics troubleshooting procedure provided by the compressor manufacturer to find a low voltage condition (i.e. one LED flash every 4 seconds).

The assessor then switches off the refrigerator, disconnects the power cable and measures a typical voltage from the solar array. The assessor carefully climbs to the solar array to inspect it. The assessor determines there is corrosion at the wiring connection between solar module interconnect cables and the solar array cable and this is causing a high resistance and excessive voltage drop. The connection is repaired, and the compressor starts cooling the refrigerator.

An assessor would enter 2 sets of cause/condition observations:

- a. In “Component” field enter “Solar array cable”
- b. In “Failure Cause” field #1 enter “Wiring connection”
- c. In “Failure Cause” field #2 enter “Corrosion”